

PATENT

U.S. Appln. Ser. No.: 09/271,024

Attorney D cket No. CONLINCO-03681

REMARKS

Claims 5-8 and 13-17 are pending in the present application. The Applicants responded to the outstanding Final Office Action on January 28, 2002. The Examiner responded by mailing an Advisory Action on February 20, 2002, maintaining all pending rejections.

The following rejections are at issue, and are set forth by number in the order that they are herein addressed:

1. Claims 5-8 and 13-17 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious under Cain *et al.* (WO97/18320);
2. Claims 5-8 and 13-17 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious under Nilsen *et al.* (U.S. Pat. No. 5,885,594) in view of Cook *et al.* (U.S. Pat. No. 5,554,646), further in view of Chin *et al.* (IDS April 13, 2000, 39); and
3. Claims 5-8 and 13-17 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious under Timmermann *et al.* (WO 98/49129, No. 25 in the IDS of April 13, 2000) in view of Cook *et al.* (U.S. Pat. No. 5,554,646), further in view of Chin *et al.* (IDS April 13, 2000, 39).

Applicants believe that the following remarks traverse the Examiner's rejection of the claims.

The Examiner Is Required To Consider All Evidence of Patentability

In their January 28, 2002, response to the outstanding Final Office Action, the Applicants brought to the Examiner's attention a reference entitled "*Variations in isomer distribution in commercially available conjugated linoleic acid*," Yurawecz, et al., Fett/Lipid, 101, Nr. 8, S. 277-282 (1999); attached hereto at Appendix 2). Applicants respectfully requested that the Examiner consider the reference for its teaching that at the time of the invention, the presently claimed compositions were not obvious under the cited art.

Applicants find the Examiner's failure to address the Yurawecz, et al. reference in the February 20, 2002, Advisory Action troublesome. Indeed, the Examiner's failure to address the majority of the Applicants' arguments necessitates their repetition in this communication.¹

¹ The February 20, 2002, Advisory Action provides the following response to the Applicants' arguments: {Applicants communication} does NOT place the application in condition for allowance because: of the reasons set forth in the prior [sic.] office action.

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In regard to the Examiner's comments concerning the use of the term "comprising" in the presently claimed compositions, Applicants respectfully submit that is the Examiner's burden to establish a valid *prima facie* case of obviousness. Applicants are simply NOT required to disprove unsupported arguments and conjecture as to what the claims could encompass.

Three Requirements Must be Met to Establish a *prima facie* Case of Obviousness by a Preponderance of the Evidence

To establish a finding of *prima facie* obviousness, the Examiner must show by a "preponderance of the evidence" that the claimed invention is obvious in view of the evidence presented by the Examiner. (MPEP §2142). "The legal standard of 'a preponderance of the evidence' requires . . . the examiner provide evidence which as a whole shows that the legal determination sought to be proved (*i.e.*, the reference teachings establish a *prima facie* case of obviousness) is more probable than not." (MPEP §2142; emphasis added).

The Examiner is well aware that are three base line requirements that **must** be satisfied in order to meet the evidentiary burdens requisite for establishing a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. A recent Federal Circuit case articulates this point. In *C.R. Bard, Inc. v. M3 Sys. Inc.*, the Federal Circuit held that providing a suggestion, teaching or motivation to combine the prior art references is "**an essential evidentiary component** of an obviousness holding." (*C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998); emphasis added). There are three

Applicants' attention is directed to the claims in the application. [sic.] the claims employ the phrase 'comprising' to define the composition, meaning the composition may comprising [sic.] ant other ingredients, including uncharacterized fatty acid, beside [sic.] the conjugated CLA. other [sic.] isomer [sic.] not specified by the claim may [sic]. in the claimed composition. Cain characterizes the CLA p rtion of the product which does not containing [sic.] the undesired CLA as specified herein [sic.].

February 20, 2002, Advisory Action, p. 2.

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sources for the requisite evidence: the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. (*Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996)). Regardless of the source of evidence, the Examiner's showing "must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not 'evidence.'" (*In re Dembiczak*, 175 F.3d 994, 1000 (Fed. Cir. 1999)). Thus, the Examiner's burden is to present "evidence" that supports the combination or modification of the cited references. This evidence must provide a "clear and particular" showing of the desirability of the modification or combination. Importantly, since an Examiner is **NOT** one skilled in the art (under the law), the Examiner's opinions as to what one skilled in the art might believe are not evidence. (*In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993) (holding "[t]he examiner's assumptions do not constitute the disclosure of the prior art."); *See also*, MPEP §2144.03). The Examiner's knowledge of relevant facts which are used to make the rejection only constitute evidence if entered into the record by affidavit. (*See*, 37 CFR 1.107(b); MPEP §2144.03).

Second, at the time of invention there was a reasonable expectation of success should the combination be carried out. (MPEP §2143.02).

Third, the references must teach or suggest every claim element. (*In re Royka*, 490 F.2d 981 (CCPA 1974); *See also*, MPEP §2143.03). This evaluation requires "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." (*In re Wilson*, 424 F.2d 1382,1385 (CCPA 1970)).

Failure to establish any one of these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicants to allowance of the claims at issue. (*See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321 (Fed. Cir. 1990)). Applicants submit that even if the references are combined (wrongfully) they do not teach every claim element. In addressing this rejection, Applicants focus on the independent claims since non-obviousness of an independent claim necessarily leads to non-obviousness of claims dependent therefrom.²

² §MPEP 2143.03.

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**The Examiner Has Overstated The Cited References And The
State Of The Art At The Time Of Filing The Present Application**

As an initial matter, Applicants submit that Examiner has overstated the cited references. Indeed, Applicants herein direct the Examiner's attention to a 1999 study conducted by the U.S. Food and Drug Administration (U.S.F.D.A.) "undertaken to determine the content and distribution of CLA isomers in commercially available CLA capsules and liquid products with labels stating to contain CLA." (*See, Yurawecz, Martin, P., et al., Variations in isomer distribution in commercially available conjugated linoleic acid,* *Fett/Lipid*, 101, Nr. 8, S. 277-282 (1999); attached hereto at Appendix 2). In brief, the Yurawecz *et al.* publication note that:

While it has not been established, which isomer(s) is (are) responsible for the reported beneficial properties of CLA, it is generally thought that anticarcinogenicity is due to rumenic acid [c9,t11 octadecadienoic acid]. **The nutritional and physiological effects, if any, of other CLA isomer(s) in commercially available CLA preparations are not known.**

(Yurawecz, *p.* 280; emphasis added). In an additional reference cited within Yurawecz *et al.*, (published by members of the Yurawecz group) it was found that the 11 *cis*, 13 *trans*-18:2 isomer was found to was found to accumulate preferentially in heart phospholipids and specifically in heart and liver diphosphatidylglycerol (DPG) of pigs feed commercial CLA mixtures. Yurawecz *et al.* note that in response to their "findings that 11 *cis*, 13 *trans*-18:2 was selectively incorporated into DPG . . . , a major supplier of commercial CLA preparations recently modified [their production] process to eliminate the 11 *cis*, 13 *trans*-18:2 isomer." (Yurawecz, *p.* 281). Thus, Applicants submit that at the time of filing the present application, those skilled in the art did not know the effects--deleterious or beneficial--of any particular CLA isomers as the Examiner has argued as a basis for combing the various references as described below.

Importantly, Yurawecz *et al.* also state in numerous paragraphs that the commercially available CLA compositions tested contained a number of different CLA isomers as well as other structurally related compounds. Yurawecz *et al.* state "the CLA products analyzed in this study were found to contain up to 12 geometric and positional CLA isomers. **These findings are based on appropriate and improved analytical methodologies** [including gas

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chromatography techniques] **that have only recently been developed.**" (Yurawecz, *p.* 281; emphasis added). Thus, it is further apparent that prior to the development of the novel methods of the disclosed in the present application, CLA compositions comprised a mixture of varying quantities of various isomers.

1. **The Present Claims Are Not Obvious Under Cain *et al.* (WO 97/18320)**

The Examiner argues that the claimed invention is allegedly obvious under Cain *et al.* for the reasons previously made of record. The Examiner further argues that the "Applicants have miss-characterized [sic] Cain *et al.* teaching. . . . Cain *et al.* have characterized all the fatty acid through gas chromatography and have identified the CLA [sic]. For example, in example 6, it state "The fatty acid composition of the product as determined by FAME GC, contained . . . 61.9% . . . CLA of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer. . . . The rest of the fatty acid are not CLA. The CLA is composed entirely of cis 9, trans 11 isomer and trans 10, cis 12 isomer (48.9% + 51.1% = 100%). No other CLA product was present" (Final Office Action, *pp.* 2-3). Applicants must disagree.

Applicants respectfully submit that the Examiner continues to misinterpret the Cain reference. The entire paragraph of the Cain *et al.* reference describing the portion of Example 6 at issue is recited below:

A solution of 600 grams of NaOH in 6 kilograms of ethylene glycol was added to two kilograms of sunflower oil. The mixture was stirred and heated at 180 °C under an inert atmosphere for 3 hours. The reaction mixture was cooled to about 90-95 °C whilst being stirred thus avoiding precipitation of solid soap. A solution of 1280 mls of HCl in 8 kilograms of demineralised water was added slowly to the reaction mixture. Then the stirring was stopped and the mixture was allowed to settle in an inert atmosphere. The pH was adjusted to 4 with HCl. The aqueous phase was separated from the oil phase. The oil phase was washed at 90 °C with two 1 liter portions of 5 % NaCL and one 2 liter portion of hot demineralised water then dried at 100 °C under vacuum. The dried oil phase was cooled to 50-60 °C blanketed with nitrogen and filtered. **The fatty acid composition of the product, as determined by FAME GC, contained 61.9 % of conjugated linoleic acid (CLA) of which 48.9 % was the cis 9, trans 11 isomer and 51.1 % was the trans 10, cis 12 isomer.**

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(WO97/18320, Example 6). It is clear from the above cited paragraph that it is unclear how much of the product was in fact fatty acids. Furthermore, it is also evident that 38.1% of the fatty acids in the product were uncharacterized.

Applicants respectfully point out that in the Example cited by the Examiner, the total fatty acid product was used to prepare acylglycerol products. Therefore, the Examiner's statement that "Cain teaches an acylglycerol composition comprising mono- di- and tri-glyceride wherein the fatty acid are c9,t11 CLA or t10,c12 CLA, no other isomer was employed for the esterification" (June 8, 2001, Office Action, page 2) is incorrect. Applicants provide further support for this assertion by directing the Examiner's attention to the Yurawecz publication discussed above. Wherein it was noted every commercial CLA preparation tested in the study contained a number (up to 12) of CLA isomers that were previously undetectable by existing analytical means.

Moreover, after the preparation of acylglycerol products, the amount of free fatty acid was described by Cain *et al.* as either 83.4% (Example 6) or 58 % (Example 7, calculated as the amount remaining from a conversion of 42% of the fatty acid product to acylglycerols). However, the reference provides absolutely no quantitation of how much of the esterified fatty acid was CLA and how much was another fatty acid. Thus, the reference does NOT indicate whether the esterified fatty acid is t10,c12 octadecadienoic acid and c9,t11 octadecadienoic as presently claimed.

The Examiner attempts to cure this inadequacy in the Cain *et al.* reference by arguing that the "optimization of the ratio of the two [CLA] moieties . . . is considered within the skill of artisan, **absent evidence to the contrary.**" (June 8, 2001, Office Action, page 2; emphasis added). Applicants submit that the Examiner's rationale for the argument that "**absent evidence to the contrary . . .**" is impermissible under MPEP rules and Federal Circuit case law. It is precisely the **evidence** indicating a *prima facie* case of obviousness that the law requires. Recent Federal Circuit cases such as *C.R. Bard, Inc.*, and *In re Dembiczak*, discussed above, state that the Examiner bears the burden of presenting **evidence** establishing beyond a reasonable doubt that the claimed invention is *prima facie* obvious. Applicants are simply **NOT** required to address or rebut the Examiner's preconceptions that are not supported by a proper evidentiary basis. Despite the legal insufficiencies of the Examiner's

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argument, Applicants have attached hereto a publication by Yurawecz *et al.* that indeed provides evidence that shows prior to the present invention optimization of CLA isomers was NOT within the skill of ordinary workers in the field.

Accordingly, Applicants respectfully remind the Examiner of their April 4, 2001, communication wherein they directed the Examiner's attention to portions of the present specification that discuss their discovery that heterogeneity and substantial batch-wise isoform variations are existing problems in conventional approaches to produce CLA products. (*See e.g.*, Specification, p. 4, ll. 9-10). The Applicants addressed these problem in CLA production by developing a **novel method** of isomerization. This novel method was used to produce the novel (and non-obvious) compositions of isomerized fatty acids which are presently being claimed.

In pertinent part, the Applicants' novel method provides a carefully controlled reaction which results in a high percentage of linoleic acid converted primarily to the conjugated c9,t11 and t10,c12 isomers so that less than about 1% of 11,13, 8,10, and trans trans isomers are present. (*See e.g.*, Specification, p. 5, ll. 5-14). The recited ratios of CLA products recited in the present claims are **in contrast** to CLA compositions produced by conventional methods. Indeed, Applicants stated that the 1% limit in concentration of the 11,13, 8,10, and trans-trans isomers serves as a convenient and practical **quality assurance standard of purity** (*See e.g.*, Specification, p. 5, ll. 11-14; emphasis added).

The Examiner further argues that the "applicants have not shown the criticality of the 1% less amounts [sic] of the 11, 13, 8, 10 or trans trans isomers to the quality of the CLA composition in term of bioreactivity or other properties." (Final Office Action, p. 3). Applicants respectfully submit that the Examiner's argument is of no moment, since the *criticality* of this element is not relevant to establishing a *prima facie* case of obviousness in the present case. Applicants respectfully submit that the criticality of a claim element (*e.g.*, a particular range) becomes a consideration only after applicants have asserted that the claimed element critically differs (*e.g.*, provides an advantage) from recitation of that element in the cited art. The Examiner has not met this standard because he has yet to point to the explicit teaching of the less than 1% 8,10 and 11,13 element in the art.

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The case of *Ex parte Wittpenn* is instructive on the criticality of an element analysis. In *Wittpenn*, the Board Of Patent Appeals and Interferences stated that:

[W]e observe that the claim is **limited** to a composition that is **non-irritating** to periocular surface tissues. Apparently recognizing the **criticality** of the pH in a composition designated to be **non-irritating** to eye tissue, the examiner holds that it would have been obvious to select the pH value of 6.9 from Roggenkamp's disclosed range of 4 to about 6.9. **However, in the absence of some motivation to select a neutral pH, the examiner's conclusion lacks any logical foundation.** . . . Accordingly, since we have been apprized of no disclosure within the Roggenkamp reference that would have led the routineer to make the critical selections to arrive at the claimed surfactant composition, we find that no *prima facie* case of obviousness has been established and that the rejection before us cannot be sustained.

(*Ex parte Wittpenn*, 16 USPQ2d 1730 (Bd. Pat. App. & Int 1990); emphasis added). The Board's conclusion in the *Wittpenn* decision was reached after having determined that *Wittpenn* purposely **limited** his claims to a pH range that was **non-irritating** to eye tissues--a critical limitation. The decision however further points out that since the examiner failed to provide the requisite motivation (*i.e.*, evidentiary support) for his argument that selecting a neutral pH was obvious, the finding of *prima facie* obviousness was withdrawn. Applicants submit that the *Wittpenn* case is instructive because it provides the Examiner an example of when an applicant's claims can be fairly said to have introduced the criticality of a claim element into prosecution, and it exemplifies the basic principle that regardless of the criticality or non-criticality of a claim element, the examiner is ALWAYS required to provide a sufficient evidentiary basis for a finding of *prima facie* obviousness. In the instant case, the Examiner has provided no evidentiary support that limiting the amounts of 8,10 and 11,13 isomers is obvious or described as being critical in the cited art.

Nevertheless, Applicants direct the Examiner's attention to the 1999 Yurawecz *et al.* publication which points at the necessity of reducing the occurrence of isomers of unknown activity in CLA compositions.

Furthermore, the Examiner has failed to show that Cain *et al.* teach or suggest a composition comprising "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R₁, R₂, and R₃, wherein said percentages are peak area percentages as determined by gas chromatography" as is

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presently being claimed. Indeed, Cain *et al.* state that their "invention concerns a new process for the preparation of CLA, wherein the ratio of cis⁹-trans¹¹/tran¹⁰-cis¹² can be chosen freely." (WO97/18320, p. 3). Applicants submit that Cain *et al.* is completely silent as to isomers of CLA other than 9,11 or 10,12 isomers specifically discussed therein. (*See e.g.*, Cain *et al.*, p. 1, ll. 17-20). Thus, the reference is silent as to the presence or absence of other octadecadienoic acids, no less specifically mentioning 8,10, 11,13, or trans trans octadecadienoic acid isomers in any amount. The Examiner has failed to establish that Cain *et al.* teach or suggest the presently claimed compositions because, as stated above, the presently claimed compositions are produced by novel methods. Applicants note that the Examiner cannot pick and choose which elements are important, and which are not from a reference(s). In order to make a *prima facie* case of obviousness, all claim limitations must be taught or suggested (MPEP 2143.03). "All words in a claim must be considered in judging the patentability of that claim against the prior art." (MPEP 2143.03, citing, *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)).

Furthermore, the results in the Applicant supplied Sugano *et al.* reference (described more fully below) suggest that the fatty acid product produced by Cain *et al.* would have a lower degree of purity than even that produced by Sugano, and that products produced as described in either reference are less pure than the fatty acid compositions recited in the presently claimed invention. In particular, Applicants submit that in their Response filed November 6, 2001, they directed the Examiner's attention to the Sugano *et al.* reference (attached to this Response at Appendix 3). This reference was compared to those cited by the Examiner. Sugano *et al.* prepared CLA by a method similar to that utilized by Cain *et al.* In both Sugano and Cain conjugation was performed in ethylene glycol at 180 °C.³ The Applicants in contrast to Sugano *et al.* and Cain *et al.* teach that the level of undesirable isomers increases with increased temperature and time of the isomerization reaction. Consequently the high temperature methods used in Sugano *et al.* produced CLA containing 18.6% trans-trans isomers and 13.7% other isomers, in addition to the c9,t11 and t10,c12 isomers. Sugano *et al.* shows that production of CLA mixtures with less than "about less than

³ The main differences Sugano *et al.* and Cain *et al.* were noted in a previous Response.

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1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid . . . " was not within the routine skill of the artisan, and certainly not suggested in the similar CLA production methods utilized in Cain *et al.* or that was even reasonably possible to do so.

For the reasons stated above, Applicants respectfully submit that the Examiner has failed to establish that Cain *et al.* fails to meet each of the three requirements for a finding of *prima facie* obviousness.

2. The Present Claims Are Not Obvious Under Nilsen *et al.* in view of Cook *et al.* and Chin *et al.*

Claims 5-8 and 13-17 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious under Nilsen *et al.* (U.S. Pat. No. 5,885,594) in view of Cook *et al.* (U.S. Pat. No. 5,554,646), further in view of Chin *et al.* (IDS April 13, 2000, 39). In particular, the Examiner argues that Applicants previous arguments regarding this combination of references was unpersuasive. The Examiner further argues that "Chin is cited to show that person [sic] of ordinary skill in the art of preparing/or isolating the pure single isomer employed herein [sic]. . . . Particularly Chin shows that isomers are separatable [sic]." (Final Office Action, pp. 3-4). Next, the Examiner argues that Applicants' conclusion that "Nilsen *et al.* is silent about other isomer [sic] and therefore is not excluded from the employing other isomer [sic] is logically incorrect. If Nilsen *et al.* is silent about the other isomer, it met [sic] the limitation of less than 1% of that isomer because no other isomer is required. . . . It is obvious to one of ordinary skill in the art to make such variation, absent evidence to show an unexpected benefit of the particular percentage." (Final Office Action, p. 4). The Examiner argues that the alleged motivation to combine the cited references can be found in the references themselves and the skill generally present in the art, because "Nielsen *et al.* teaches [sic] acylglycerol compositions wherein the fatty acid moiety may be 9, 11 or 10, 12 CLA, Cook *et al.* teaches [sic] that 9, 11, and 10,12 CLA employed herein [sic] are known to be beneficial for animal health. . . . Therefore, it is *prima facie* obvious to make an acylglycerol wherein the fatty acid moiety is a combination of two known CLA isomers because all the

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isomers are known to be similarly useful." (Final Office Action, pp. 4-5). Applicants must respectfully disagree.

The Examiner has repeatedly stated that Nilsen *et al.* has been cited to teach a composition comprising c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid (Office Action, page 3). Applicants respectfully point out that the presently claimed invention comprises t10,c12 octadecadienoic acid and c9,t11 octadecadienoic acid. The Examiner has yet to show that the Nilsen *et al.* reference teach a composition comprising any amount of the t10,c12 octadecadienoic acid isomer. Applicants submit that this is because the Nilsen reference never mentions the t10,c12 octadecadienoic acid isomer. Indeed, Nilsen defines the conjugated linolenic acids contemplated therein as follows:

The term "conjugated polyunsaturated fatty acid residue", as used herein, is defined as fatty acid compounds, having 16 to 22 carbon atoms, and at least two double bonds, wherein said double bonds alternate with single bonds. Various positional and geometric isomers of conjugated polyunsaturated fatty acid residues involving the double bonds exist and are meant to be included herein. The conjugated polyunsaturated fatty acid residue octadecadienoic acid (18:2) is also known as conjugated linoleic acid (**9-cis, 11-trans-octadecadienoic acid and/or 10-cis, 12-trans-octadecadienoic acid**)

(Nilsen *et al.*, col. 4, ll. 2-6). The above definition makes clear that Nilsen *et al.* specifically defines the octadecadienoic acid isomers (*i.e.*, conjugated linoleic acid) employed therein as being limited to the **"9-cis, 11-trans-octadecadienoic acid and/or 10-cis, 12-trans-octadecadienoic acid"** isomers. Consequently, Nilsen *et al.* never mention the 8,10,11,13, and the trans-trans octadecadienoic acid isomers, no less compounds comprising the presently recited levels of these isomers. Should the Examiner maintain that Nilsen *et al.* do teach these isomers, Applicants respectfully request the Examiner to provide citations reciting chapter and verse where the isomers can be found.

In regard to Nilsen *et al.* Applicants respectfully submit that the Examiner's argument that **"if Nilsen is silent about the other isomer, it met [sic] the limitation of less than 1% of that isomer. . . ."** (Final Office Action, p. 4). In view of the Examiner's failure to cite chapter and verse where Nilsen *et al.* teach a composition comprising the t10,c12 octadecadienoic acid isomer, Applicants assume that the "silent" isomer(s) referred to by Examiner include each of the following presently claimed elements t10,c12 octadecadienoic

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acid; and "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R₁, R₂, and R₃." The gist of the Examiner's argument is that Nilsen *et al.* teach these elements absent evidence of the contrary. The Federal Circuit has repeatedly held that the Examiner's assumptions do not constitute evidence establishing any of the requirements for a finding of *prima facie* obviousness. As shown above, the Examiner's logic for arguing that it can be assumed a reference teaches an element of the claimed invention "absent evidence to the contrary" has been repudiated by a number of decisions in the Federal Circuit. As shown above in the discussion of Yurawecz *et al.*, is doubtful that Nilsen *et al.* has purity of "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid isomers" as recited in the pending claims.

Furthermore, the Examiner admits that Nilsen *et al.* do not expressly teach and are not enabled for the specific amounts of each of the two presently claimed isomers, c9,t11-octadecadienoic acid and/or t10,c12-octadecadienoic acid, or the employment of the composition in animal feed. (*See*, June 8, 2001, Office Action, *p.* 3).

Applicants again respectfully point out that Chin *et al.* do not teach what the Examiner states that it does, and that it is irrelevant to the presently claimed invention. Chin *et al.* do not teach how to prepare or isolate single pure isomers; instead, *p.* 697, left column, to which the Examiner refers simply shows scans from a gas chromatographic separation of a sample of fatty acids. The conditions are not given, so it is not possible to know how to separate the fatty acids. Samples analyzed by gas chromatography are generally very small, and not of suitable amounts for subsequent chemical reactions. It is likely that the fatty acids are detected by flame ionization, which destroys the sample, and is thus the opposite of "preparing /or isolating" the fatty acids as stated by the Examiner.

In response to the Applicants' previous arguments regarding Chin *et al.*, the Examiner simply asserts that "Chin is cited to show that person [sic] of ordinary skill in the art of preparing/or isolating the pure single isomer employed herein [sic]. . . . Particularly Chin shows that isomers are separatable [sic]." (Final Office Action, *pp.* 3-4). Consequently, the Examiner has failed to address and specifically rebut the Applicants' previous arguments. However, in this response, Applicants further stress that a reference must enable what it is

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cited as teaching. "In order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method." (*Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547 (Fed. Cir. 1989)). Applicants submit for the reasons stated above that Chin is not enabled for the propositions cited by the Examiner. Again, as noted above, the Yurawecz *et al.* publication further rebuts the Examiner's argument that Chin *et al.* teach how to, or even that, the art was capable of isolating single CLA isomers prior to the present invention.

Moreover, Chin *et al.* is directed to observing the amount of certain--that is not 8,10, 11,13, or trans trans octadecadienoic acid isomers--in tissues obtained from sacrificed rats feed a diet of free or esterified linoleic acid. Chin *et al.* conspicuously fail to even mention these isomers. Therefore, Applicants submit that Chin *et al.*, is directed to basic research regarding fatty acid metabolism and end product accumulation in rats; Chin *et al.* is not analogous to the field of the present invention. The case of *In re Oetiker*, Federal Circuit held that:

The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. . . .

(*In re Oetiker*, 24 USPQ 2d 1443 (Fed. Cir. 1992)). Applicants submit that the Examiner's citation of Chin *et al.*, given the non-analogous nature of its teachings, must be based upon an impermissible hindsight reconstruction of the present invention. Thus, Chin *et al.* is simply irrelevant to the presently claimed invention and there was no motivation to combine it with the other cited references.

Furthermore, Applicants note that the Examiner's argument regarding the Chin *et al.* reference that "the quantity of purified compounds is not relevant since the instant claimed composition would read on any amount of compounds" is unclear. (Final Office Action, *p.* 4). Applicants note, however, that the Examiner's argument implicitly acknowledges that Chin *et al.* fails to teach the quantity of any purified compounds, no less the quantities of the particular CLA isomers presently recited in the pending claims.

For the reasons stated above, Applicants respectfully submit that Chin *et al.* fail to teach every element of the presently claimed invention even if combined (improperly) with the other cited references.

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In regard to Cook *et al.*, Applicants submit that this reference also fails to mention the 8,10 and trans trans octadecadienoic acid isomers. To the extent Cook *et al.* discuss the 11,13 octadecadienoic acid isomers, the reference explicitly recognizes that these isomers are produced in the disclosed methods. The reference does not say that these isomers will only occur in trace amounts. Moreover, the reference **does not** teach or suggest any levels for the 8,10 and trans-trans octadecadienoic acid isomers in the disclosed compounds, let alone levels of "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid" as are presently recited in the pending claims.

The Applicants next point out that the Examiner's discussion of the references above does not indicate how all of the claim elements are taught or suggested by the combination of the references. Thus, the Examiner does not assert that the combination teaches or suggests a composition characterized in containing t10,c12 octadecadienoic acid, and c9,t11 octadecadienoic acid, at positions R₁, R₂, and R₃, as is presently claimed. The Examiner also asserts that the optimization of the ratio of the compounds is considered within ordinary skill; however, this assertion is not true for the reasons stated above.

The Examiner concludes that a motivation to combine the references is that c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid are known to be useful in food products. This is not a motivation to combine these two particular references to arrive at the claimed combination; at most, it is a conclusory statement that such a combination might be desirable. Nor has Examiner provided any reasonable expectation that even combining the two references would result in the Applicants' presently claimed invention. Therefore, the Examiner has failed to make a *prima facie* case of obviousness, and the Applicants respectfully request that the rejection of the claims over Nilsen *et al.* in view of Cook *et al.* and further in view of Chin *et al.* be withdrawn.

3. The Present Claims Are Not Obvious Under Timmermann *et al.* in view of Cook *et al.* and Chin *et al.*

Claims 5-8 and 13-17 stand rejected under 35 U.S.C. §103 as allegedly obvious under Timmermann *et al.* (WO 98/49129, No. 25 in the IDS of April 13, 200) in view of Cook *et al.* (U.S. Pat. No. 5,554,646), further in view of Chin *et al.* (IDS April 13, 2000, 39). The

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Examiner implicitly relies upon his previous arguments to substantiate this rejection. (*See*, June 8, 2001, Office Action, *pp.* 4-5). Applicants must respectfully disagree.

Numerous legal flaws in the Examiner's rejections based on the *Cook et al.* and *Chin et al.* references were discussed above. As were the other factual flaws in the Examiner's arguments in view of the teachings of the *Yurawecz et al.* publication. The Examiner's addition of the *Timmermann et al.* reference to those of *Cook et al.* and *Chin et al.* is likewise flawed and does not further the Examiner's argument that the presently claimed invention is allegedly *prima facie* obvious.

In particular, the Examiner has asserted that *Timmermann et al.* teach a composition for food comprising acylglycerol compounds where the fatty acid is conjugated linoleic acid, and admits that this reference does not teach expressly the specific isomers [as in the presently claimed invention] (June 8, 2001, Office Action, *p.* 4). The Examiner further asserted that *Cook et al.* "teach that both c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid, and that their mixture is beneficial for animal health." (June 8, 2001, Office Action, *p.* 4). The Examiner then concluded that it would have been obvious to make the composition of *Timmermann et al.* with acylglycerol compounds wherein the fatty acid moiety is a mixture of about equal amounts of c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid, and employ the composition for animal feed. The Examiner also stated that *Chin et al.* was cited to show that "a person of ordinary skill possesses the skill of preparing/or isolating the single isomer employed" in the invention. (June 8, 2001, Office Action, *p.* 5).

The Applicants first point out that *Chin et al.* do not teach what the Examiner states that it does, and that it is irrelevant to the presently claimed invention, for the reasons cited above. The Applicants next point out that the Examiner's discussion of the references does not indicate how all of the claim elements are taught or suggested by the combination of the references. Thus, the Examiner does not assert that the combination teaches or even suggests a composition characterized in containing t10,c12 octadecadienoic acid, and c9,t11 octadecadienoic acid, at positions R₁, R₂, and R₃, as is presently claimed. The Examiner also asserts that the optimization of the ratio of the compounds is considered within ordinary skill, but this is not true for the reasons stated above. The Examiner also appears to be completely ignoring an element of the claims, which is that the R groups of the acylglycerol comprise

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"about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-octadecadienoic." Since the Examiner does not indicate how the combination of references would result in this claim element. Because the Examiner has not shown how the combination teaches or suggests all of the claim elements, the Examiner has not met this requirement to make a *prima facie* case of obviousness, and on this ground alone the claims are not obvious.

Moreover, the Examiner concludes that a motivation to combine the references is that c9,t11-octadecadienoic acid and/or c10,t12-octadecadienoic acid are known to be useful in food products. This is not a motivation to combine these two particular references; at most, it is a conclusory statement that such a combination might be desirable. The Yurawecz *et al.* publication further rebuts the Examiner's arguments concerning what was known about CLA products and particular CLA isomers.

In regard to the Examiner's statement that "[t]he instant claims are directed to a composition comprising old and well-known compounds. The motivation to make such compositions is clear and obvious to one of ordinary skill in the art as shown in the cited references," not only is the Examiner's conclusory and completely lacking the required evidentiary basis for a finding of *prima facie* obviousness, the basis of the Examiner's statement (*i.e.*, that the composition is presumptively obvious because it is comprised of allegedly known compounds) has been thoroughly repudiated by the Federal Circuit. For example, the Federal Circuit has held that "[o]nly God works from nothing. Men must work with old elements." (*Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 225 USPQ 26, 31 n. 3 (Fed. Cir. 1985), quoting Markey, "Why Not the Statute," 65 JPOS 331, 333-334 (1983)). Moreover, the Federal Circuit has also determined that it is not legally proper to focus on individual substitutions and differences instead of on the invention as a whole. (*Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed.Cir. 1986), cert. denied, 480 U.S. 947 (1987)).

For the reasons stated above, Applicants submit that the Examiner has failed to establish that the presently claimed invention is *prima facie* obviousness under the cited references. Accordingly, Applicants respectfully request that this rejection be withdrawn.


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CONCLUSION

All grounds of rejection of the Final Office Action of November 29, 2001, have been addressed, and therefore reconsideration of the application is respectfully requested. It is respectfully submitted that the claims are in condition for allowance. Should the Examiner have any questions, or if a telephone conference would aid in the prosecution of the present application, the Applicants encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: May 10, 2002
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